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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,458	03/27/2001	Geoffrey S. Martin	2409.3273.3US	2544

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EXAMINER

SIRMONS, KEVIN C

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/819,458	Applicant(s) MARTIN ET AL.	
	Examiner Kevin C. Sirmons	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-30 and 42-45 is/are pending in the application.
 4a) Of the above claim(s) 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-29 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Drawings (Third Time)

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: an outer tube; an inner tube; a first septum; a second septum; a second lumen; a second aperture; and a third aperture. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The specification is objected to because reference character "48" has been used to designate both a second septum and a third septum. Correction is required.

The specification is objected to because reference character "52" has been used to designate both a first lumen and a second lumen. Correction is required.

Applicant should call the examiner to clarify any questions regarding the objections (not rejections) to the drawings.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-29, ~~31~~ and 42 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ekholmer U.S. Pat. No. 4,717,379.

Ekholmer discloses an outer tube having a proximal end and a distal end (6); an inner tube (5) having a proximal end and a distal end defining there within a first lumen (2), said inner tube having an outer diameter less than the inner diameter of said outer tube (fig. 3), said inner tube being disposed within said outer tube to define an interior space between the outside of said inner tube and the inside of said outer tube (fig. 3), the inner diameter of said inner tube being sized as to accommodate an insertion guide wire having an outer diameter in a range from about 0.036 inches to about 0.038 inches (It is the examiner's position that the inner tube is sized to accommodate the aforementioned guide wire without destroying the device of Ekholmer. Furthermore, it would have been an obvious matter of design choice to change the dimension of the catheter and/or insertion guidewire (which is not claimed) so that the inner tube can accommodate an insertion guidewire, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Additionally, applicant has not disclosed that the dimensions of the guidewire solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any guide wire sized to fit into Ekholmer's catheter; a first septum; a second septum; a second lumen; a third lumen; a tapered distal tip; a first, second and third (figs. 1-3); as to claims 26-29 and 31, (fig. 1-3);

As to claim 25, Ekholmer discloses a catheter substantially as claimed except for the size of the inner diameter of the inner tube is about 0.04 inches. It would have been an obvious matter of design choice to change the dimension of the catheter so that the inner tube, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Furthermore, applicant has not disclosed that the dimensions of the inner tube solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well the catheter as disclosed by Ekholmer.

Response to Amendment

Claim Rejections - 35 USC § 112

As to claim 24, has clarified the language of the claims in his arguments, however, applicant failed to define and give reference numerals for the claimed subject matter within the specification. Therefore, the 112 rejections are withdrawn and the objections remain.

Specification (Second Time)

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Applicant has provided antecedent basis for the claimed subject matter.

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See an outer tube; an inner tube; a first septum; a second septum; a second lumen; a second aperture; and a third aperture. Therefore, the objection has been withdrawn.

Response to Arguments

Applicant's arguments filed 6/10/05 have been fully considered but they are not persuasive.

In response to applicant's arguments, the recitation an insertion guide wire has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In response to applicant's argument that an insertion guide wire, a recitation of the intended use and/or functional language of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use or functional language, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

The examiner submits that applicant's preamble does not breath life and meaning into claim 1. Furthermore, the device of Ekholmer is fully capable of performing the functions set forth in claim 1.

As to applicant's arguments on pages 13 and 14, with regard to claim 24, Ekholmer clearly discloses applicant's claimed subject matter as in complete detail as contained in independent claim 24. Moreover, the examiner has failed to find in Ekholmer where applicant structure may result in uneven distribution of lubricant or localized cleaning, both of which applicant alleged contradict the teaching of Ekholmer. Applicant has failed to specifically indicate these facts by column and line number. Additionally, applicant appears to want to limit and/or define the number of septum's, lumens and/or tubes in Ekholmer. However, the facts indicate that these numbers can be anything greater than two, since that is what plurality means. Further, applicant clearly indicated that he is not limited to the embodiments illustrated, which is what it appears applicant seems to indicate in his response (pages 14 and 15).

Again, as to applicant's arguments regarding the guidewire. First, applicant has not claimed a guidewire whatsoever! Further, the Examiner asserts that substantially the majority of catheters that have a lumen have the ability to be used with a guidewire. This fact clearly includes Ekholmer's catheter. Nowhere in Ekholmer does it indicate that a guidewire teaches away from the device or destroys the device.

As to claim 25, applicant has basically further defined a guidewire, which he has not claimed. The reason why the examiner rejected the claims under 102/103 is because Ekholmer clearly anticipates, however, this fact may not be clear to some such

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as yourself. That's where the 103 part comes to play. Changing the size of catheters and/or guidewire is not novel or new and can be regarded as obvious as clearly shown in your current rejection.

As to claim 27, see (fig. 1-3); as to claim 29, if the lumens disclosed do not have a C-shaped transverse cross section as what is disclosed in applicant's drawings, then, the examiner would certainly like to know what is the shape of the transverse cross section of Ekholmer?

As to claim 42, see above rejections and arguments. Furthermore, applicant has provided the examiner with absolutely no evidence supporting his position that inserting a guidewires into a body cavity would irritate the mucous membranes that are specifically intended for protection by the invention of Ekholmer.

Finally, the examiner submits that a second lumen located on one side of a transverse cross section of the first septum, the inner tube, and the second septum, and a third lumen located on an opposite side of the transverse cross section of the first septum, the inner tube, and the second septum would not result in uneven distribution of lubricant or localized cleaning. For example, if the number of septums and lumens change, the number and placement of holes could stay the same or increase and vary to cover all areas of the body cavity. Changes to the number of elements are within the scope of the invention.

As to claim 24 and 42, see examiner response to arguments on 12/6/04.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 571-272-4965. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin C. Sirmons
Primary Examiner
Art Unit 3763
8/8/05

Kevin C. Sirmons